

13 DIC. 2022

N DE LOTE:

0091222

	FORM	MD.128/H
	CERTIFICATE OF ANALYSIS	Rev. 12 of June 17 th , 2019 Pag. 1 of 1
REFERENCE TO PROCEDURE:	PO.10/H	

28/09/2022

CERTIFICATE OF ANALYSIS

Lysozyme Hydrochloride
Date production:
Retest date:
Ref:

Batch No. 003/22
24/08/2022
23/08/2025
TR-S-220912-00125-1

<u>Physical and Chemical tests:</u>	SPECIFICATIONS	RESULTS	METHODS
Identification 1	Complies	Complies	[JPXVII]
Identification 2	Complies	Complies	[JPXVII]
Appearance	White powder	Complies	[JPXVII]
Clarity of solution	Clear	Clear	[JPXVII]
Solubility	Freely soluble in water, and practically insoluble in ethanol	Freely soluble in water, and practically insoluble in ethanol	[JPXVII]
Loss on drying	≤ 8.0 %	2.1 %	[JPXVII]
Assay_Purity total protein content	≥ 95.0 % [IN HOUSE SPECIFICATIONS]	97.5 %	[EPS005]
Assay_Potency:	≥ 0.9 mg/mg (d.b.)	0.9 mg/mg	[JPXVII]
pH	3.0-5.0	3.0	[JPXVII]
Chlorides	≤ 3.5 % [IN HOUSE SPECIFICATIONS]	3.4 %	[EPS001]
Residue of ignition	≤ 2.0 %	0.2 %	[JPXVII]
Nitrogen	≥ 16.8 % ≤ 18.6 %	17.2 %	[JPXVII]

Microbiological tests:

Total Aerobic Microbial Count	<100 ufc/g	30 ufc/g	[EP07/2010:20612]
Total Combined Yeast/Moulds Count	<100 ufc/g	<10 ufc/g	[EP07/2010:20612]
Salmonella	Absent/ 10 g	Absent	[EP04/2010:20613]
Escherichia Coli	Absent/ 1 g	Absent	[EP04/2010:20613]
Bile Tolerant Gram-Bacteria	Absent/ 1 g	Absent	[EP04/2010:20613]

Note: The analytical methods used are in compliance with the current editions of pharmacopoeias.

Manufacturing activities have been conducted in compliance with the GMP requirements.

Qualified Person

E.P.S. S.p.A.
EGG POWDER SPECIALISTS
Via Mensa, 3
48022 S. Maria in Fabbrigo (RA) - ITALY
Cod. Fisc. n° P.IVA 01267400290